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Delegations will find attached Commission document D020513/02.

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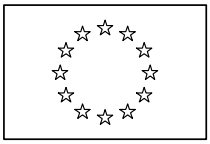

EUROPEAN COMMISSION

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COMMISSION DIRECTIVE ../…/EU

of XXX

amending certain headings of Annex I to Directive 98/8/EC of the European Parliament and of the Council

(Text with EEA relevance)

COMMISSION DIRECTIVE ../…/EU

of XXX

amending certain headings of Annex I to Directive 98/8/EC of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market[1], and in particular Article 11(4) and Article 16(2) thereof,

Whereas:

(1) Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market[2] provides detailed rules for the evaluations of existing active substances. Article 15(2) of the Regulation provides for peer reviews by experts from the Member States prior to the Commission decisions on inclusion in Annex I.

(2) Pursuant to Article 10(2)(i) of Directive 98/8/EC, inclusion of an active substance in Annex I shall, where appropriate, be subject to requirements on the minimum degree of purity and the nature and maximum content of certain impurities.

(3) The first inclusion in Annex I was decided in Commission Directive 2006/140/EC of 20 December 2006 amending Directive 98/8/EC of the European Parliament and of the Council to include sulfuryl fluoride as an active substance in Annex I thereto[3]. That Directive defined the headings of Annex I to Directive 98/8/EC. Those headings include "Minimum purity of the active substance in the biocidal product as placed on the market".

(4) In the context of the peer reviews provided for by Article 15(2) of Regulation (EC) No 1451/2007, Member States experts have developed a method for establishing the similarity of the chemical compositions and the hazard profiles, known as "technical equivalence", of substances falling within the same definition but being produced from different sources or manufacturing processes. For this establishment, the degree of

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1 OJ L 123, 24.4.1998, p. 1.
2 OJ L 325, 11.12.2007, p. 3.
3 OJ L 414, 30.12.2006, p. 78.

purity is only one of the factors that can be decisive. Furthermore, lower purity of an active substance does not necessarily compromise its hazard profile.

(5) It is therefore appropriate to replace the existing reference to minimum purity in the headings of Annex I to Directive 98/8/EC by a reference to the minimum degree of purity of the active substance used for the evaluation made in accordance with Article 11 of the Directive, and indicate that, in the product placed on the market, the active substance may be of a different purity provided that it has been proven technically equivalent with the evaluated substance.

(6) The first row of Annex I to Directive 98/8/EC established by Commission Directive 2006/140/EC also contains the heading "Deadline for compliance with Article 16(3) (except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)".

(7) According to Article 4(1) of Directive 98/8/EC, a Member State receiving an application for mutual recognition of an existing authorisation has a period of 120 days to authorise the product through mutual recognition. However, if the first authorisation of a product is granted less than 120 days before the deadline for compliance with Article 16(3) of the Directive for that product, a Member State receiving a complete application for mutual recognition of that authorisation cannot comply with the deadline for compliance with Article 16(3) of the Directive if it uses the 120 days period provided for by Article 4(1) of the Directive, even if the complete application for mutual recognition was submitted without delay after the granting of the first authorisation.

(8) For products for which the first authorisation is granted later than 120 days before the original deadline for compliance with Article 16(3) of Directive 98/8/EC, it is therefore appropriate to extend Member States' deadline for complying with Article 16(3) of the Directive by mutually recognising the first authorisation to 120 days after the submission of the complete application for mutual recognition, provided that the complete application for mutual recognition has been submitted within 60 days of the granting of the first authorisation.

(9) Furthermore, in a situation where a Member State proposes, within the deadline for compliance with Article 16(3) of the Directive, to derogate from mutual recognition of an authorisation in accordance with Article 4(4) of the Directive, that Member State's compliance with Article 16(3) of the Directive within that deadline can be impossible, and will depend on the date when the Commission decision on the matter is adopted in accordance with the second subparagraph of Article 4(4) of the Directive. In such cases, the deadline should therefore be suspended until a reasonable period after the Commission decision has been adopted.

(10) For products for which one or more Member States have proposed to derogate from mutual recognition in accordance with Article 4(4) of Directive 98/8/EC, it is therefore appropriate to extend Member States' deadline for complying with Article 16(3) of the Directive by mutually recognising the first authorisation to thirty days after the adoption of the Commission decision.

(11) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 98/8/EC is amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 March 2013 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

   When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the Commission
The President
José Manuel BARROSO

ANNEX

In Annex I to Directive 98/8/EC, the first row, which contains the headings to all entries, shall read as follows:

No	Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance[4]	Date of inclusion	Deadline for compliance with Article 16(3), unless one of the exceptions indicated in the footnote to this heading applies[5]	Expiry date of inclusion	Product type	Specific provisions (*)

[4] The purity indicated in this column was the minimum degree of purity of the active substance used for the evaluation made in accordance with Article 11. The active substance in the product placed on the market can be of equal or different purity if it has been proven technically equivalent with the evaluated substance.

[5] For products containing more than one active substance covered by Article 16(2), the deadline for compliance with Article 16(3) is that of the last of its active substances to be included in this Annex. For products for which the first authorisation has been granted later than 120 days before the deadline for compliance with Article 16(3) and a complete application has been submitted for mutual recognition in accordance with Article 4(1) within 60 days of the granting of the first authorisation, the deadline for compliance with Article 16(3) in relation to that application is extended to 120 days after the date of reception of the complete application for mutual recognition. For products for which a Member State has proposed to derogate from mutual recognition in accordance with Article 4(4), the deadline for compliance with Article 16(3) is extended to thirty days after the date of the Commission Decision adopted in accordance with the second subparagraph of Article 4(4).